Attachment 1

Attorney Docket SMI-005.01

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Isa Odidi and Amina Odidi	:	Paper No.:
Serial No.	09/166,701	:	Group Art Unit: 1617
Filed:	October 5, 1998	:	Examiner: Webman, Edward J.
For:	**Controlled Release Pharmaceutical Delivery Device and Process For Preparation Thereof**		

DECLARATION UNDER 37 C.F.R. 1.132

Box Fee Amendment
Commissioner for Patents
Washington, DC 20231

Isa Odidi and Amina Odidi declare that:

1. They are co-inventors of and are familiar with the present U.S. Patent Application Serial No. 09/166,701, and they are familiar with the Official Actions issued in the present application and the reference cited by the Examiner; U.S. Patent No. 4,610,870 to Jain *et al.*

2. The controlled release pharmaceutical device and the pharmaceutical composition of the present invention comprise, amongst other components, hydroxyethylcellulose and hydroxypropylmethyl cellulose.

3. U.S. Patent No. 4,610,870 to Jain *et al.* is directed to a controlled release pharmaceutical formulation containing a core portion. The core includes a medicament and a hydrocolloid gelling agent. The hydrocolloid may comprise cellulose polymers which are cellulose ethers such as methyl cellulose, cellulose alkyl hydroxylates such as

hydroxypropylmethyl cellulose, hydroxypropylcellulose, hydroxymethylcellulose or hydroxyethylcellulose.

4. In order to demonstrate that cellulose derivatives are not interchangeable with respect to the present invention, data is provided in Tables 1 and 2 for hydroxypropylmethyl cellulose (HPMC), ethylcellulose (EC), and hydroxyethylcellulose (HEC).

Table 1 Formulation of Model Drug using Different Cellulose Derivatives

Formulation	HPMC 15%	HEC 15%	EC 15%
Model Drug	50%	50%	50%
HPMC	15%	0%	0%
HEC	0%	15%	0%
EC	0%	0%	15%
Lactose	44%	44%	44%
Magnesium Stearate	1%	1%	1%

Table 2 Results from Dissolution studies of the Model Formulations

Time	HPMC 15%	HEC 15%	EC 15%
0	0	0	0
1	16.9	60	88.1
2	25	68	88.2
4	43	75.6	88.3
5	50	78.4	88.4
6	53.4	80	88.5
7	63.3	83.5	88.6
8	66.5	83.2	88.6
10	78.4	88.8	90
11	80.4	87.5	90
12	81.2	84.7	90
13	89.7	90	90
14	92	90	90

5. The amount of drug released in 1 hour is 17% for HPMC, 60% for HEC and 88% for EC. It was also observed that EC tablets broke up in 30 minutes. The time taken for 70% of the drug (i.e., $T_{70\%}$) to be released was about 9 hours for HPMC, 4 hours for HEC and 30 minutes for EC. These results clearly indicate that HPMC, HEC and EC are not interchangeable.

6. These results show that the release rates of the drug depends on the cellulose polymer used. Therefore, since these tests show that cellulosic polymers listed in U.S. Patent No. 4,610,870 to Jain *et al.* are not equivalent in combination with the present invention, one skilled in the art would not assume equivalency of the listed cellulose polymers in combination with the present invention.

7. Isa Odidi and Amina Odidi further declare that all statements made herein of his/her own knowledge are true and that all statements made on information and

belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

4 November ,2003

Isa Odidi

November 4 , 2003

Amina Odidi